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Public Health Service
Food and Drug Administratic

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

February 8, 2002

Our Reference: 2951040

Akira Otani, President
United Fishing Agency, Limited
117 Ahui Street
Honolulu, Hawaii 96813

WARNING LETTER

Dear Mr. Otani:

We inspected your seafood processing facility, located at the above address, on July 16 and 21, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. The deficiencies cause your histamine forming fish and fishery products such as tuna, Mahi-mahi, Wahoo, and Marlin, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that the fish have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. We listed some of the deficiencies on a Form FDA 483 (Inspectional Observations) and discussed them with Brooks H. Takenaka, Treasurer/Assistant General Manager, at the conclusion of the inspection. We are providing a copy of the FDA 483 for your reference. Your serious HACCP deficiencies were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for Fresh Whole and Dressed Pelagic Fish including tuna, Mahi-mahi, Marlin, and other histamine forming fish, lists critical limits at the Receiving critical control point (CCP) that are not adequate to control histamine formation. Specifically:

    (a) The critical limit listed for fish received less than 12 hours after death is not adequate to control histamine. Checking the adequacy of ice is not discouraged. However, this parameter does not ensure that icing was accomplished onboard the vessels in a timely fashion. Internal temperature can be used, in relation to the known time of death and the ambient sea and air temperature conditions, to ensure that appropriate and rapid chilling methods were used onboard the harvest vessel to prevent bacterial growth and histamine formation.

Further, assessment of the time lapse from the time of death to the time of receipt, as it pertains to determining the applicable critical limit, should be made on the lot as a whole or on portions of the lot as necessary, not only on the basis of the time since the **last** fish was caught. Your "Letter[s] of Assurance," including page 2 of the "Sign-in Guard Report" do not account for this proper assessment. To make matter worse, the reporting on some of the "Letter[s] of Assurance" is erroneous. For examples:

a) On 6/25/01, fish were offloaded from the [redacted] The Letter of Assurance declared the date of the last fish caught as of 6/20/01 but identified the time since the last fish caught as "less than 12 hours;" and

b) On 7/16/01, fish were offloaded from the [redacted] The Letter of Assurance declared the date of the last fish caught as 7/11/01 but identified the time since the last fish caught as "12 to 24 hours."

(b) The critical limit concerning the presence of decomposition as measured by sensory evaluation does not list an actionable limit. The presence of decomposition in fish delivered to the primary processor should act as an alarm that the fish were harvested and handled onboard the vessel in a manner that resulted in bacterial growth and may have resulted in histamine formation. Culling of decomposed fish from the receiving lot does not ensure that fish containing elevated levels of histamine will be identified and removed from commerce. FDA recommends establishing a critical limit that sensory examination of a representative sample of fish show no more than 2.5% decomposition in the sample.

2. You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for "Fresh whole and dressed, pelagic fish including tuna (spp), Mahi-mahi, marlin, fish that are susceptible to forming histamine" lists monitoring procedures that are not adequate to control histamine formation. Specifically:

a) At the receiving critical control point, your HACCP plan describes monitoring for the presence of decomposition on "each fish as it is displayed and sold." You also state that sensory evaluations will be conducted by the "scale master, auctioneer, and/or QC staff," "in addition, each buyer judges quality." Your plan should be more specific in identifying who in the firm will be responsible for the evaluation as well as record-keeping at the time of **receipt**. Further, assessments of organoleptic "quality" of individual fish while being sold at auction does little to assist your firm in determining if the fish received from a particular vessel contain excessive histamine. Nor would it allow you to effectively prevent the suspect fish from entering commerce.

b) At the cold storage critical control point, your firm monitors the temperature of the storage rooms by checking thermometers [redacted] per day. For refrigerated storage, FDA recommends **continuous** monitoring with visual checks of the measuring instrument a least once per day. Alternatively, for product stored under ice or chemical cooling media, FDA recommends a visual check for the adequacy of ice or chemical cooling media surrounding the product at least twice per day.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for "Fresh whole and dressed, pelagic fish including tuna (spp) mahimahi, marlin, fish that are susceptible to forming histamine" Receiving and Cold Storage CCPs are not appropriate to control histamine formation. Specifically:

   a) At the Receiving critical control point, your corrective action requires that you reject fish that exceed [redacted]F. However, your plan calls for re-sampling, presumably at the same monitoring frequency, until a sample is discovered that is within the critical limit, rejecting only individual fish that happened to be found with elevated temperatures during the course of sampling. This is not appropriate corrective action. When you find fish with internal temperatures exceeding the critical limit, you should assume that the fish were not handled properly by the vessel and elevated histamine levels could exist in the lot. When the internal temperature critical limit is exceeded, FDA recommends that you reject the lot, or perform histamine analysis on a minimum of 60 fish, rejecting the lot if any fish is found with histamine greater than or equal to 50 ppm.

   b) Similarly, your corrective action plan for exceeding the critical limit for decomposition at the Receiving critical control point is not appropriate. Rejecting only those fish found to contain odors does not ensure that accepted fish do not have elevated histamine levels. When the sensory critical limit has been violated, FDA recommends that you reject the **lot**, or perform histamine analysis to determine the acceptability of the **lot**.

   c) At the Cold Storage CCP, your corrective action plan calls for immediate product control. However, you have no provisions to determine product safety and disposition of potentially hazardous product. When a deviation in the storage critical limit occurs, in addition to immediate corrective action, FDA recommends that you destroy the product, divert the product to a non-food use, or perform histamine analysis to determine the acceptability of the lot.

   d) In addition, none of your corrective actions at the Receiving critical control point ensure that the cause of the deviation is corrected. In addition to ensuring that the affected product does not enter commerce, FDA recommends that you discontinue use of the supplier until evidence is obtained that the vessel's harvesting and handling practices have been improved.

4. You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limit employing the use of the VSOP at the Receiving CCP to control the hazard of histamine formation. During the July 2001 inspection, and in your July 21, 2001 "Response to FDA Inspection Report (Form 483)," your firm admitted that it did not accomplish the quarterly verification procedures listed in your HACCP plan. Moreover, the verification records you submitted, dated September 8, 2000, from [redacted] show that your HACCP histamine controls were **not** functioning to prevent receipt of fish with elevated levels of histamine, i.e., 3 of the 14 samples had histamine levels greater than 50 ppm (99 to 170 ppm).

Your "VSOP" critical limit and "LOA" monitoring approach as means of controlling histamine in fresh scombrotoxin-forming fish at the receiving critical control point were identified as objectionable conditions during the inspection of your firm. These serious deficiencies are the subject of a Citizen's Petition submitted by your firm in August 2001 requesting enforcement discretion under FDA's Transition Policy procedure. The petition is currently under review by the agency. Until a final decision on the petition is rendered, the agency will exercise enforcement discretion and is not specifically itemizing these deficiencies in this Warning Letter. However, since 1999, the agency has expressed serious concerns about these deficiencies to your firm. Your consideration of the agency's decision on the Citizen's Petition as it applies to your HACCP program and these observed deficiencies will be very important to you.

We acknowledge the delay in issuing this letter. However, the HACCP deficiencies listed above are significant and must be brought to your attention.

Sufficient time has passed since our inspection of July 2001 and our presentation of the FDA-483 Inspectional Observations to Mr. Takenaka, to correct the violations at your facility. If you have not made the corrections, you must immediately take appropriate steps to correct the violations. We may initiate regulatory action without further notice if you do not correct them. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please advise us in writing, within fifteen (15) working days of receipt of this letter, the measures you have taken to correct the deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of completed monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Charles D. Moss Acting DD

for Dennis K. Linsley
District Director
San Francisco District

Enclosure: Form FDA 483

cc: Brooks H. Takenaka, Treasurer